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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,964	03/18/2005	Donald S Copland	SHI-003FORus	9029
7590 Smith Brandenburg & Novak 905 Ohio Pike Cincinnati, OH 45245				
EXAMINER JOY, DAVID J				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
05/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,964

Applicant(s)

COPLAND ET AL.

Examiner

David J. Joy

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Claims 1 and 7-25 are pending as amended on February 11, 2008, with Claims 2-6 having been cancelled. Claim 1 is withdrawn from consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendments

3. Applicant's amendment to the specification, filed February 11, 2008, with respect to stating the invention of the instant application, has been fully considered and will be entered.
4. Applicant's amendment to Claims 10-18, filed February 11, 2008, obviates the previously cited rejection under 35 U.S.C. §112. As such, the rejection of Claims 10-18 under 35 U.S.C. §112, second paragraph, as being indefinite, has been withdrawn. Likewise, the rejection of Claims 24 and 25 under 35 U.S.C. §112, second paragraph, as being indefinite, has also been withdrawn.

Claim Objections

5. Claims 1 and 12 are objected to because of the following informalities: With regard to Claim 1, though it is currently withdrawn from consideration, the claim recites "an epidermal surfactant that has *beem* applied" in the first and second lines of the claim. As for Claim 12, the

amendments to the claim are noted. However, given that the claim carries the status identifier that it is "(Currently Amended)" the amendments should have been properly presented, in that the additions to the claim (that were not present in the previous version of the claim) should have been shown as underlined text; specifically, the addition of the words is and comprising should have appeared as underlined text in the claim. Appropriate correction is required in the former, and Examiner wanted to bring the latter to Applicant's attention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The independent claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
8. Claim 7 recites "a substrate having an image applied to the surface of said substrate" and "a surfactant placed along said surface of said substrate." The newly-added limitations are not supported by the specification. While the examiner appreciates Applicant's response to the rejection under 35 U.S.C. § 112, second paragraph, against Claim 7, that was set forth in the

Office Action mailed on November 1, 2007, there appears to be no support for such changes in the specification as originally filed.

9. Claims 8-25 are rejected accordingly, as they all depend upon Claim 7.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 7 recites "a surfactant placed along said surface of said substrate". As it is written, it is unclear as to where exactly the surfactant is placed or positioned on the invention. Claim 7 also recites that the "image is effective for indicating the quantity of effectiveness of said surfactant." While the specification recites this language, it is unclear as to what this limitation is meant to convey, as the statement that something is *effective for indicating effectiveness* is rather indefinite (emphasis added).

12. Claims 8-25 are rejected accordingly, as they all depend upon Claim 7.

Claim Rejections - 35 USC § 102

13. Claims 7-9, 11-21 and 23 stand rejected under 35 U.S.C. 102(e) as being anticipated by the U.S. Patent Application Publication of Godbey et al. (2002/0187181; hereinafter “Godbey”).

14. Godbey teaches an article for applying and monitoring a surfactant/surface active agent that comprises a substrate (the carrier), an image positioned on the surface of the substrate (part of the one or more surface active agents in the layer/portion), and a surfactant deposited on the substrate (the one of more active agents) (see Abstract; see also ¶¶ [0001], [0004], [0005], [0007], [0008], [0019] and [0020]; see also Claim 1, et seq.). Godbey also teaches that the active agent can be associated with the carrier or adhesive as a coating applied to a surface of the carrier or adhesive and that the article can be used for such treatments as delivery of pharmaceutical treatments like drugs, hormones, antimicrobial agents, as well as cosmetic treatments such as the delivery of hair or skin colorants and transfer of designs, masks, tattoos or appliqué (see ¶¶ [0013], [0014] and [0017]). Thus, it follows that if an active agent can be incorporated into the article along with an image such as a design, mask, tattoo or appliqué, then the proper transfer of the image to the skin would result in the proper delivery of the active agent associated therein. In addition, Godbey teaches that the surfactant is an epidermal surfactant (see ¶¶ [0006] and [0020]). Further, Godbey teaches that the surfactant can consist of any of the surfactants taught in the instant application (see ¶¶ [0004], [0005], [0013], [0021], [0047]-[0049] and [0052]).

15. Godbey teaches that the image/decal is water-soluble and that it can be a material that is vegetable-based, compressed sugars, compressed salts, polymers and oligomers and gelatin (see

¶¶ [0024], [0045] and [0047]). Godbey recites these materials with regard to the composition of the carrier film/substrate, but as the image is associated with the carrier, it follows that the image will also be incorporated into these materials (see ¶ [0014]). In addition, Godbey teaches that the substrate/carrier is a material that can absorb and retain the surfactant that is provided thereon, such as paper, natural cloth, synthetic cloth, synthetic sponge, woven materials and non-woven materials (see ¶¶ [0019], [0024], [0029]-[0033] and [0045]).

16. Godbey also teaches that the article comprises an adhesive, as a means of securing the article to the skin of the user (see Abstract; see also ¶¶ [0008], [0019] and [0034]-[0041]). In addition, Godbey teaches that a single article can comprise one active agent or that the article can also comprise multiple active agents (see ¶ [0044]). Therefore, if one of the active agents is to be an image, and the other agent is a different type of agent/surfactant, it follows that as the surfactant either wears off of, or is absorbed into, the skin of the user, then the image that is present could very easily fade or become more visible, depending on the nature of the surfactant that is covering the image portion of the article (see e.g., ¶¶ [0033] and [0050]).

Claim Rejections - 35 USC § 103

17. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey, as applied to Claim 7 above, and further in view of either applicant's admissions or the U.S. Patent Application Publication of Dole et al. (2003/0044366; hereinafter "Dole").

18. Godbey teaches the claimed structure of the article as discussed above. In addition, Godbey recites a general teaching that the image can comprise colorants, dyes or printing (see ¶ [0033]). However, Godbey is silent as to the specific types of inks used to provide these colors or images. Applicant states that the ink is to be selected from a group of inks that are all well-known in the art. Alternatively, Dole, drawn to a composition that changes color, recites that there are a myriad of colorants that can be used that will effectuate a color-change (see ¶¶ [0012] and [0013]). Likewise, Dole teaches that the colorant can cause a color change as a surfactant dissipates (see *Id.*) Since Godbey, Dole and the instant application are all drawn to related fields of invention, and they all address the specific use of the same surfactants on the skin of the user, it would have been obvious to a person having ordinary skill in the art to use the inks, especially in a color-changing composition, that are claimed in the instant application.

Response to Arguments

19. Applicant's arguments filed on February 11, 2008 have been fully considered but they are not persuasive.

20. Applicant argues that a review of the Examiner's citations does not show an image or even a teaching or a suggestion of the desirability of an image effective for indicating the quantity of effectiveness of the surfactant. However, it is noted that in addition to the portions cited by Examiner, Applicant should also consider the reference as a whole. Godbey teaches that the surfactants ("active agents") are any agent providing any treatment to a user of the article, and that the active agents include topical pharmaceutical agents, systemic pharmaceutical agents

and cosmetic agents (see ¶ [0013]). In addition, Godbey recites that the active agents can be associated with the carrier or the adhesive layer by incorporating an agent into or depositing an agent onto a carrier or an adhesive layer, or as a coating applied to the surface of the carrier of adhesive (see ¶ [0014]). Further, Godbey provides that the treatment provided by the article/agent shall be any desired effect provided by an active agent to a user (see ¶ [0017]). Therefore, it follows that the device (or, article) can have an active agent that is of a decorative nature associated with the carrier and an active agent that is a pharmaceutical agent associated with the adhesive, and that the article can enable the user to transfer the decorative agent to one's skin or to the skin of another and in doing so, the complete transfer of the image will also result in the effective transfer of the pharmaceutical agent to the same skin. Thus, by knowing that the treatment provided by the article results in the effective transfer of the image, the user can also know that any/all other agents have also been delivered, thereby providing an indication as to the effective delivery of those other agents as well. Likewise, after the delivery of the image and the agent, with continued exposure of the skin to the device, the treating agent will continue to be delivered to the skin and once the image fades, that will provide either the user or one monitoring the delivery with an indication that the continued delivery/absorption of the treatment agent is also beginning to wane. Thus the effectiveness of the treatment can not only be signaled to the user by the initial transfer, but also the effectiveness of a continuous treatment through an ongoing exposure that is easy to monitor.

21. Applicant further argues that Godbey does not teach, suggest or disclose an image effective for indicating the quantity or effectiveness of the surfactant, and there is no showing

that one skilled in the art would be motivated to combine the teachings of Godbey and Dole to arrive at the claimed invention. The teachings of Godbey have already been discussed hereinabove. As for the combination of Godbey and Dole, the Dole reference teaches that the different types of inks recited in Claim 10 are known in the art, and that it is also known that using these inks can result in a color change that will occur as the ink is either exposed to or subject to prolonged exposure to the skin of the user. While Dole specifically discusses the color change in terms of the sufficient drying of the application containing these inks, Dole also recites that the color change can be used to signal that the application has been left on long enough to provide the desired properties that the application is meant to deliver to the skin (see e.g., ¶ [0007]). As for Godbey, it is taught that the article is meant to provide treatment to the user, and that treatment refers broadly to the desired effect provided by an active agent to the user (see ¶ [0017]). Thus, taken together, the article taught by Godbey, which is meant to provide treatment to the user, when combined with the teachings of Dole, which recites that a color change is one way of signaling that an exposure has been for a sufficient duration, would show one skilled in the art that it would have been obvious at the time of invention that a color change could be used as a way of signaling the effective delivery of a surfactant to the skin of a user. Note that while Dole does not disclose all the features of the present claimed invention, Dole is used as a teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 U.S.P.Q. 224, 226 (C.C.P.A. 1973); *In re Keller* 624 F.2d 413, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981). Rather, this reference teaches a certain concept and in combination with the primary reference discloses the presently-claimed invention.

22. Finally, Applicant argues that in order to establish a prima facie case of obviousness, the three criteria of the “teaching, suggestion, or motivation” test (“TSM Test”) must be met. Applicant (or Applicant’s representative) is reminded that the TSM Test is not the only way to establish a prima facie case of obviousness, given the ruling in the case of *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q. 2d 1385, 127 S.Ct. 1727 (U.S. 2007).

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Joy whose telephone number is (571)272-9056. The examiner can normally be reached on Monday - Friday, 7:00 AM - 3:30 PM EST.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie E. Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DJJ/
Examiner, Art Unit 1794
04/30/2008

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794